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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,101	02/04/2004	Jacques Seguin	CVALVE.006CP1	6184

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EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,101	SEGUIN ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3+ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) *5-11,17-30,34,35 and 46-78* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/04/2004* is/are: a)☒ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Attachment A*.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 12-15, 31-33, 36-38, 44, 45, 92, 93, 96-104, and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaolian et al. (US Patent No. 6,299,637). Shaolian discloses the following regarding claim 1: a prosthetic valve assembly (40) for use in replacing a deficient native valve, the valve assembly comprising (col. 2, lines 55-58): a valve having a base (see attachment A), a plurality of commissure points (see attachment A), and a plurality of resilient leaflets (76, 78); a valve support (44) configured to be collapsible for transluminal delivery (col. 5, lines 36-37) and comprising a first (50) and a second (52) portion, said first portion expandable to contact the anatomical annulus of the native valve (30) when the assembly is properly positioned, said second portion supporting the base and the commissure points of the valve (52; Figures 7, 8); and a radial restraint for controlling a diameter of the second portion (col. 5, lines 55-67) the radial restraint comprising a wire (col.5, lines 7-9; col. 6, lines 31-36; Figures 1, 4, 6-8).

Shaolian discloses the following regarding claim 2: the valve assembly wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter (col. 5, lines 55-67).

Shaolian discloses the following regarding claim 3: the valve assembly wherein the radial restraint is capable of substantially resisting collapse below a preset diameter (col. 7, lines 6-10).

Shaolian discloses the following regarding claim 4: the valve assembly wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter (col. 7, lines 6-10; col. 5, lines 55-67).

Shaolian discloses the following regarding claim 12: the valve assembly further comprising a drug-eluting component (col. 11, lines 9-12).

Shaolian discloses the following regarding claim 13: the valve assembly further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment (col. 5, lines 60-67).

Shaolian discloses the following regarding claim 14: the valve assembly of wherein the valve support comprises at least one wire (col. 5, lines 7-9; col. 6, lines 31-36).

Shaolian discloses the following regarding claim 15: the valve wherein the valve support comprises a single length of wire (col. 6, lines 63-64).

Shaolian discloses the following regarding claim 31: a prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve (col. 2, lines 55-58), the valve assembly comprising an axial valve support (44) portion configured to support a prosthetic valve having at least one leaflet (76, 78) and to prevent substantial interference with the positioning and/or operation of the prosthetic valve (40) by any residual components of the native valve (30), including calcified native components (col. 5, lines 16-27), said support portion comprising at least one radial restraint at a first section of said support portion (50) to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic valve leaflets and to prevent significant regurgitation (col. 6, lines 30-40) and a second section (52) configured to expand in situ for pushing the residual native valve components against the native annulus and surrounding tissue (30), wherein the second section is configured to expand to a diameter different from that of the first section (52) (col. 5, lines 37-49; Figures 1, 4, 6).

Shaolian discloses the following regarding claim 32: the valve assembly wherein the radial restraint is configured to reduce recoil (col. 5, lines 36-41, 49-54).

Shaolian discloses the following regarding claim 33: the valve assembly wherein the radial restraint comprises a mechanical stop (col. 5, lines 60-67).

Shaolian discloses the following regarding claim 36: the valve assembly wherein said second section is configured to be expanded by a balloon catheter (col. 6, line 42, U.S. Pat. No. 5,800,508 incorporated by reference).

Shaolian discloses the following regarding claim 37: the valve assembly wherein said second section is configured to be expanded beyond its yield point in situ (col. 10, line 58- col. 11, line 2).

Shaolian discloses the following regarding claim 38: the valve assembly further comprising a stent configured to expand in situ for pushing against the residual native valve components (col. 8, lines 39-42).

Shaolian discloses the following regarding claim 44: the valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (col. 5, lines 63-67).

Shaolian discloses the following regarding claim 45: the valve assembly wherein said radial restraint comprises a wire (col. 6, lines 30-36).

Shaolian discloses the following regarding claim 92: a prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve (30) (col. 2, lines 55-58), the valve assembly comprising an axial valve support portion (50, 52, 54) configured to support a prosthetic valve (40) having at least one leaflet (76, 78) and to prevent substantial interference with the positioning and/or operation of the prosthetic valve (40) by any residual components of the native valve (30), including calcified native components (col. 5, lines 16-27), said support portion comprising at least one radial restraint at a first section of said support portion (50) to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of the prosthetic valve leaflets and to prevent significant regurgitation (col. 6, lines 30-40), and a second section configured to expand in situ for pushing the residual native valve

components against the native annulus and surrounding tissue (30), wherein the second section is configured to expand to a diameter different from that of the first section beyond its yield point in situ by a balloon catheter (col. 6, line 42, U.S. Pat. No. 5,800,508 incorporated by reference; col. 5, lines 37-49; Figures 1, 4, 6).

Shaolian discloses the following regarding claim 93: the valve assembly further comprising a stent configured to expand in situ for pushing against the residual native valve components (col. 8, lines 39-42).

Shaolian discloses the following regarding claim 96: the valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (col. 5, lines 63-67).

Shaolian discloses the following regarding claim 97: the valve assembly wherein said radial restraint comprises a wire (col. 6, lines 30-36).

Shaolian discloses the following regarding claim 98: a prosthetic valve assembly configured for endoluminal delivery to replace a deficient native valve (col. 2, lines 55-58), the valve assembly comprising an axial valve support portion configured to support a prosthetic valve (50, 52, 54) having at least one leaflet (76, 78) and to prevent substantial interference with the positioning and/or operation of the prosthetic valve by any residual components of the native valve (30, 40), including calcified native components (col. 5, lines 16-27), said support portion comprising at least one radial restraint at a first section of said support portion (50) to preclude expansion when deployed in situ substantially no greater than a preset diameter to increase coaptivity of

the prosthetic valve leaflets and to prevent significant regurgitation (col. 6, lines 30-40), wherein said radial restraint comprises a wire (col. 6, lines 30-36; Figures 1, 4, 6).

Shaolian discloses the following regarding claim 99: the valve assembly wherein the radial restraint is configured to reduce recoil (col. 5, lines 36-41, 49-54).

Shaolian discloses the following regarding claim 100: the valve assembly wherein the support portion further comprises a second section (52) configured to expand in situ for pushing the residual native valve components against the native annulus and surrounding tissue (30) (col. 5, lines 37-49; Figures 1, 4).

Shaolian discloses the following regarding claim 101: the valve assembly wherein the second section (52) is configured to expand to a diameter different from that of the first section (50) (col. 5, lines 36-42; Figure 4).

Shaolian discloses the following regarding claim 102: the valve assembly wherein said second section is configured to be expanded by a balloon catheter (col. 6, line 42, U.S. Pat. No. 5,800,508 incorporated by reference).

Shaolian discloses the following regarding claim 103: the valve assembly wherein said second section (52) is configured to be expanded beyond its yield point in situ (col. 10, lines 58-60; Figure 4).

Shaolian discloses the following regarding claim 104: the valve assembly further comprising a stent configured to expand in situ for pushing against the residual native valve components (col. 8, lines 39-42).

Shaolian discloses the following regarding claim 110: the valve assembly further comprising at least one anchor configured to exert sufficient radial forces against the lumen wall to prevent substantial migration (col. 5, lines 63-67).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 79-86, 90, and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaolian et al. in view of Chandrasekaran et al. (US Patent No. 6,210,408). In claims 16, 79-86, and 90 '637 does not disclose a decrease in the wire's thickness to lessen the radial expansion force. '408, however teaches the following regarding claim 16: the valve assembly wherein at least one portion of the single length of wire has a reduced thickness to decrease the radial expansion force (col. 4, lines 1-2).

In claim 79, '637 discloses the following: a prosthetic valve assembly (40) for use in replacing a deficient native valve (30), the valve assembly comprising (col. 2, lines 55-58): a valve having a base (see attachment A), a plurality of commissure points (see attachment A), and a plurality of resilient leaflets (76, 78); a valve support (44)

configured to be collapsible for transluminal delivery (col. 5, lines 36-37) and comprising a single length of wire (col. 6, lines 63-64), a first portion (52) and a second portion (54), said first portion expandable to contact the anatomical annulus of the native valve (30) when the assembly is properly positioned, said second portion supporting the base and the commissure points of the valve (50 or 54); and a radial restraint for controlling a diameter of the second portion (col. 5, lines 36-41; Figures 1, 4, 6). '637 does not disclose a wire whose thickness reduces to decrease radial expansion force. However, '408 teaches the following: the single length of wire has a reduced thickness to decrease the radial expansion force (col. 4, lines 1-2).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 80: the valve assembly wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter ('637, col. 5, lines 55-60).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 81: the valve assembly wherein the radial restraint is capable of substantially resisting collapse below a preset diameter ('637, col. 7, lines 6-10).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 82: the valve assembly wherein the radial restraint is capable of substantially resisting expansion beyond a preset diameter and substantially resisting collapse below a preset diameter ('637, col. 5, 55-58; col. 7, lines 6-10).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 83: the valve assembly wherein the radial restraint comprises a wire ('637, col. 6, 31-36).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 84: the valve assembly wherein the radial restraint comprises a thread ('637, col. 6, 31-36).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 85: the valve assembly wherein the radial restraint comprises a mechanical stop ('637, col. 5, 63-67).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 86: the valve assembly wherein the radial restraint comprises material from which at least a portion of the valve support is made so that the second portion does not expand beyond a preset diameter ('637, col. 5, 55-60; col. 7, lines 6-10).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 88: the valve assembly wherein the radial restraint comprises a cuff (50, 52, 54)('637, col. 6, lines 52-56; Figure 4).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 90: the valve assembly further comprising a drug-eluting component ('637, col. 11, lines 9-12).

Shaolian et al., in view of Chandrasekaran et al., discloses the following regarding claim 91: the valve assembly, further comprising an anchor for engaging the lumen wall when expanded in place for preventing substantial migration of the valve assembly after deployment ('637, col. 5, lines 60-67).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a wire whose thickness decreases as a way to reduce the radial expansion force in the implant.

Claims 87 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaolian et al. in view of Chandrasekaran et al. as applied to claims 16, 79-86, 90, and 91 above, and further in view of Kocur (US Patent No. 6,350,277). Shaolian et al. and Chandrasekaran et al. do not disclose the use of a shape memory material as described by the applicant in claim 87. However, '277 teaches the use of nitinol, which is a shape memory material (col. 6, lines 36-39) that will assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a shape memory material such as nitinol to assist the prosthetic valve to better fit in the area where it is replacing the deficient native valve.

Shaolian et al. and Chandrasekaran et al. do not disclose the use of stent specifically configured to cooperate with the valve support to preclude recoiling as described by the applicant in claim 89. However, '277 teaches the use of such a stent (col. 3, lines 16-26) to preclude recoil in the valve support. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to cooperate with the valve support system to preclude recoiling.

Claims 39-43, 94, 95, and 105-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaolian et al. in view of Kocur. Shaolian et al. discloses the use of a stent with the valve system, but does not disclose all of the specific features of the stent as described by the applicant in claims 39-43, 94, 95, and 105-109.

Kocur discloses the following regarding claim 39: the valve assembly wherein the stent is self-expanding (col. 3, lines 21-23).

Kocur discloses the following regarding claim 40: the valve assembly wherein the stent is configured to be expanded by a balloon catheter (col. 9, lines 48-53).

Kocur discloses the following regarding claim 41: the valve assembly further composing a stent configured to reduce the recoil of the support portion following self-expansion of the support portion (col. 3, lines 16-26).

Kocur discloses the following regarding claim 42: the valve assembly wherein the stent is configured to reside within the valve support portion when deployed (col. 5, lines 55-60).

Kocur discloses the following regarding claim 43: the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60).

Kocur discloses the following regarding claim 94: the valve assembly wherein the stent is configured to reside within the valve support portion when deployed (col. 5, lines 55-60).

Kocur discloses the following regarding claim 95: the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60).

Kocur discloses the following regarding claim 105: the valve assembly wherein the stent is self-expanding (col. 3, lines 21-23).

Kocur discloses the following regarding claim 106: the valve assembly wherein the stent is configured to be expanded by a balloon catheter (col. 9, lines 48-53).

Kocur discloses the following regarding claim 107: the valve assembly further comprising a stent configured to reduce the recoil of the support portion following self-expansion of the support portion (col. 3, lines 16-26).

Kocur discloses the following regarding claim 108: the valve assembly wherein the stent is configured to reside within the valve support portion when deployed (col. 5, lines 55-60).

Kocur discloses the following regarding claim 109: the valve assembly wherein the stent is configured to reside outside the valve support portion when deployed (col. 6, lines 56-60).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a stent configured to these specifications to allow the stent to work more efficiently with the prosthetic valve system.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
July 21, 2006

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER

Attachment A

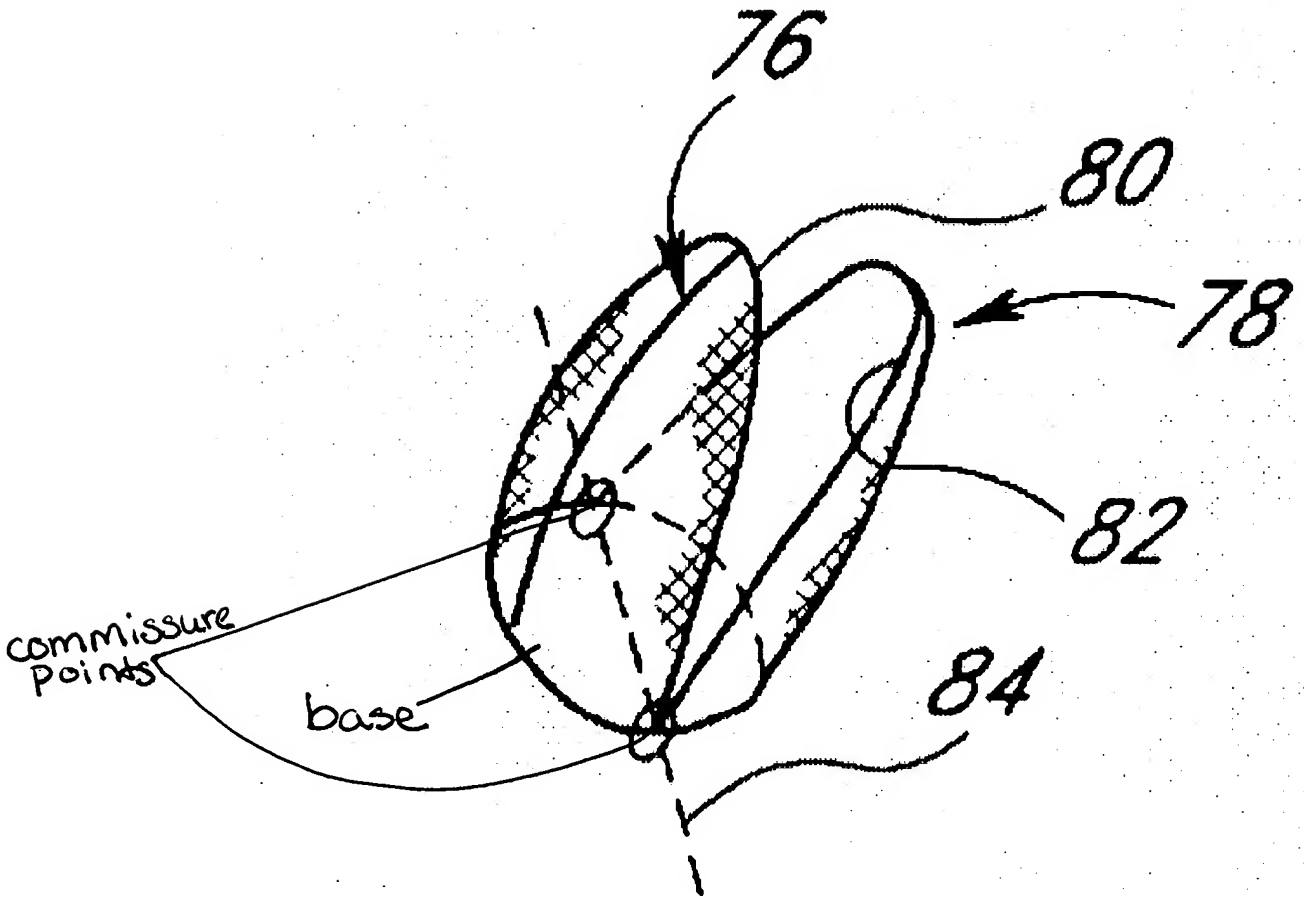

FIG. 6